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No. 06-372

IN THE

SUPREME COURT OF THE UNITED STATES

FERRING B.V., PETITIONER,

–AND–

AVENTIS PHARMACEUTICALS, INC., PETITIONER,

v.

BARR LABORATORIES, INC., RESPONDENT.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF

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October 3, 2006

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CORPORATE DISCLOSURE STATEMENT

Petitioners' corporate disclosure statement was set forth at page *ii* of their Petition for a Writ of Certiorari, and there are no amendments to that statement.

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Contrary to Barr's misleading rhetoric, Petitioners are not requesting "abolition"[1] (Resp. Br. 2) of the inequitable conduct doctrine. Rather, Petitioners are appropriately asking this Court to restore reasonable limits to the judicially-created doctrine, which this Court has applied only once, more than sixty years ago, in a case of egregious misconduct by a patent applicant. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945). Because the inequitable conduct doctrine has the draconian effect of rendering unenforceable otherwise valid patents, and because the Federal Circuit has transformed the doctrine into a rote defense asserted against virtually every patentee seeking to enforce its intellectual property rights, this case presents important questions of public interest that are long overdue for consideration by this Court.

Barr's opposition brief is most notable for the key points it does not contest. Barr does not dispute that *Precision* is the only case in which this Court has held a patent unenforceable on the basis of misconduct before the PTO; that courts interpreted *Precision* narrowly for at least two decades; that circuit splits on both the "materiality" and "intent" issues that define the doctrine accompanied its expansion beginning in the 1970s; that such expansion of the doctrine beyond *Precision* is justified neither by decision of this Court nor by act of Congress; that the doctrine is based solely on inherent judicial power; and that, as broadly interpreted now by the Federal Circuit, the doctrine has no known counterpart in any other area of administrative law.

The Petition raised these points, supported by a mountain

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[1] In fact, rather than Petitioners, some of the nation's preeminent institutions are urging such a drastic course absent reform. The Petition notes these recommendations (Pet. for Cert. 28-30) to highlight the importance of the specific legal issues presented to this Court.

of authority, to underscore the importance of the questions presented and, correspondingly, the need for certiorari. Rather than challenging these points, Barr argues that Petitioners supposedly failed to raise the relevant legal issues below; that circuit splits on patent issues are no longer relevant; and that this case is not the right vehicle for deciding the questions presented. However, Petitioners' two presented questions (concerning the proper scope of the materiality and intent standards in inequitable conduct cases) track precisely the issues presented to and decided by the courts below. In addition, the acknowledged long-standing circuit splits and demonstrated fissures between the Federal Circuit and the PTO further support review by this Court.

Finally, Barr attempts to obscure the significant legal issues raised here by devoting much of its brief to a distorted version of the "facts," which are not in the lower courts' opinions and which are, for the most part, beside the point here. This case clearly presents the Court with an excellent and much needed opportunity to clarify the inequitable conduct doctrine.

I. Petitioners' Questions Are Properly Presented

The questions presented in the Petition concern the scope of the materiality and intent showings required to establish inequitable conduct. These issues were squarely presented to the Federal Circuit and were at the heart of that court's decision. Indeed, almost all of the legal analysis in the majority opinion (App. 10a-24a) is devoted to the scope of the materiality and intent standards.

The Federal Circuit understood that Petitioners were espousing a "narrow view of materiality" that does not encompass information about past personal and professional relationships having no bearing on the substantive issues of patentability. (App. 13a.) The Federal Circuit rejected

Petitioners' materiality standard in favor of one that allows information about a declarant to be considered material if the information might be considered relevant for impeachment purposes under the "general law of evidence." (App. 11a.) This reasoning, articulated and applied by the majority below, set an extremely low threshold for materiality, and it is precisely this holding for which Petitioners seek review.

Similarly, the intent issue raised in Petitioners' second question—whether the intent necessary for inequitable conduct can be based as a matter of law on a "should have known" standard—clearly was briefed and decided below. Petitioners' briefing at the court of appeals expressly argued that mere "oversight" or "negligence . . . would not satisfy the legal requirements for inequitable conduct intent." (Ferring Fed. Cir. Br. 51-52.) Nevertheless, the Federal Circuit held on summary judgment that the requisite intent threshold can be met as a matter of law where an omission is deemed to be "highly material" and the patent applicant "knew or should have known" of the materiality of the omission. (App. 19a.) In a dissent that Barr utterly fails to address, Judge Newman specifically objected to the majority going "too far" in holding as a matter of law that deceptive intent may be established based on "what an inventor 'should have known.'" (App. 41a.) And in seeking rehearing below, Petitioners again argued that the intent element of inequitable conduct cannot be established as a matter of law on the basis of a negligence or "should have known" standard. (Aventis Fed. Cir. Reh'g Pet. 8-10.)

Barr's procedural default arguments also disregard the nature of a petition for certiorari. Certiorari petitions are directed, not to the merits of the case, but rather to the importance of the questions presented, the existence of conflicting authorities, and other factors that demonstrate the need for Supreme Court review. This Court's own rules require certiorari petitions to brief matters—such as the

importance of the issues presented and the need for Supreme Court review—that are not the focus of a merits brief in a Court of Appeals. *See* Sup. Ct. R. 10 & 14.1(h); *see also* ROBERT L. STERN ET AL., SUPREME COURT PRACTICE 354 (7th ed. 1993) (noting a certiorari petition is "unlike any other form of appellate advocacy" because the "question at the certiorari stage is where and when the Court ought to be making law") (internal quotations omitted). Thus, the Petition in this case recites the historical development of the inequitable conduct doctrine, the acknowledged splits between the Federal Circuit and other regional circuits, and the tension between the Federal Circuit's inequitable conduct doctrine and the PTO standards governing the patent prosecution process.[2]

II. The Dramatic Expansion of the Inequitable Conduct Doctrine, Circuit Splits, and Inconsistent Federal Circuit Doctrine Warrant Certiorari

Barr cannot dispute that, under Federal Circuit law, the inequitable conduct doctrine has been dramatically expanded

[2] Barr's reliance on Supreme Court precedent to support its waiver argument (*see* Resp. Br. at 13) is misplaced. This Court granted certiorari in all of the cases Barr cites, and the issues the Court declined to review in each related to legal issues separate and distinct from those raised below. For example, in the first case Barr cites, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 n.4 (2002), the Court declined to consider whether federal maritime law governed a tort action where the case had been litigated below under state tort law and the only federal issue previously raised involved statutory preemption. Similarly, the Court did not hint in any of Barr's other cited cases that a certiorari petition is barred from citing a broad set of legal materials to demonstrate the importance of the legal issues litigated below. There also is no merit to Barr's suggestion that, because patent infringement appeals are heard by a single court, this Court should apply a heightened standard in such cases in determining whether an issue was vetted sufficiently below. (*See* Resp. Br. 16.)

from the doctrine recognized in *Precision* and *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944). This Court held the patents unenforceable in *Precision* because the inventor had concededly committed perjury in filing a false oath about the scope of his invention and in *Hazel* because applicant's counsel had fabricated an article cited to both the agency and the courts in support of patentability. Thus, this Court has held patents unenforceable only where there were misrepresentations directly impacting patentability, and those misrepresentations were knowingly and willfully made.

Here, however, the Federal Circuit held that omissions regarding prior relationships between certain of the declarants and Ferring were "highly material" (App. 16a), even though they did not bear on patentability, and that those omissions constituted inequitable conduct under a "should have known" standard of intent. Indeed, the substance of the declarations was unchallenged and was supported by an additional declarant with no previous relationship with Ferring.[3] Barr, however, fails to distinguish between the materiality of the *substance of the declarations* and the materiality of the undisclosed prior connections between three of the declarants and Ferring. (*See* Resp. Br. 2, 20.)

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[3] Barr's extensive characterization of the "facts" fails to mention that the applicants supported their positions with declarations from Dr. Myron Miller, a widely published researcher who had no connections with Ferring, past or present. (*See* App. 4a, 6a.) Barr further asserts that the inventor substantially drafted the declarations in dispute in whole or in part (Resp. Br. 2). This was not a basis for the Federal Circuit's materiality finding (*see* App. 13a-18a), and with good reason: As the Seventh Circuit has observed, "[a]lmost all affidavits submitted in litigation" are not drafted by the affiants. *Russell v. Acme-Evans Co.*, 51 F.3d 64, 67 (7th Cir. 1995). The important thing is that a declarant agree with the statements in a declaration, something not challenged here.

While the scientific information in the declarations may have related to the patentability issue before the PTO, information regarding past employment or research relationships between Ferring and some of the declarants (all "respected non-inventor scientists" (App. 35a)) did not.

Barr also does not dispute that there are circuit splits as to both materiality and intent which pre-date the Federal Circuit, but instead argues that the formation of the Federal Circuit in 1982 resolved all the conflicts. The vigorous dissent below by Judge Newman, the three votes in favor of rehearing *en banc*, the muddled Federal Circuit case law since *Kingsdown* (*see* Pet. for Cert. 20-21), and the widespread criticism of the doctrine of inequitable conduct (*see e.g.*, Pet. for Cert. 12 n.6, 29 n.16) prove otherwise.

Moreover, the Federal Circuit acknowledged earlier this year that information may qualify as "material" under any one of its five different materiality standards. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006). And cases after *Digital Control* confirm the Federal Circuit's disregard of the PTO's standard of materiality even with respect to patent applications filed after 1992. *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 176 Fed. Appx. 117, 119 (Fed. Cir. 2006); *Cordis Corp. v. Boston Scientific Corp.*, Nos. 05-1418, 05-1432, 2006 U.S. App. LEXIS 16621, at *6 (Fed. Cir. June 29, 2006); *see also Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1384 (Fed. Cir. 2006) (Newman, J., dissenting) ("The panel majority further states . . . that it need not follow the criteria of the PTO's rule. . . as recently revised. That revision was adopted after public hearings, and exploration of extensive experience as well as the needs and balance of patent examination. That revision binds the PTO and, absent sound reason, the Administrate Procedure Act requires this court to follow it uniformly."). Having multiple materiality standards, as the Federal Circuit does, only creates needless

confusion. *See, e.g., Zoltar Satellite Alarm Sys., Inc. v. Snaptrack, Inc.*, No. C 01-20291 JW, 2006 U.S. Dist. LEXIS 46486, at *9-12 (N.D. Cal. July 10, 2006) (court required patentee to assess materiality using all five standards).

Barr's attempt to dismiss the regional circuit splits as "stale" also ignores that this Court has pointed to circuit splits pre-dating the creation of the Federal Circuit as a valid reason for granting certiorari. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). Moreover, notwithstanding the formation of the Federal Circuit, there remain instances in which other appellate courts may encounter patent law issues. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring) (noting that "other circuits will have some role to play in the development of [patent] law" and that "[a]n occasional conflict in decisions may be useful in identifying [patent] questions that merit this Court's attention").

Finally, Barr contends that Congress is better suited to decide the scope of the inequitable conduct doctrine. Yet the very case cited by Barr demonstrates that this Court is willing to decide the scope of non-constitutional doctrines, even though in all such cases Congress could legislate the doctrine "out of existence any time it chooses." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) (ruling on the scope of the patent doctrine of equivalents). Moreover, it is especially appropriate for this Court to make clear the scope of a doctrine it created as an exercise of inherent judicial power.

III. The Long-Running Conflict between the PTO and the Federal Circuit Justifies Certiorari Here

Barr errs fundamentally in arguing that this Court should wait for a different inequitable conduct case because this one "involves the PTO's *pre*-1992 regulations." (Resp.

Br. 21, emphasis in original.) Inequitable conduct cases are *not* brought pursuant to agency rules and are *not* brought to enforce agency rules. Rather, the inequitable conduct doctrine is based on inherent judicial power to enforce the "equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision*, 325 U.S. at 814. The standard of materiality is judicially controlled.

Nevertheless, in fashioning the judicial standard of materiality, courts may—and indeed should—look to the agency's rules and pronouncements in making a pragmatic judgment about what information is material to the agency's processes. In this case, the PTO's pre-1992 rule defined materiality to include information that "a reasonable examiner would consider . . . important" in deciding whether to allow a patent to issue. 37 C.F.R. § 1.56(a) (1991). In 1992, the PTO revised Rule 56 "to present a clearer and more objective definition of what information the Office considers material to patentability." Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. 2021-02, 2024 (Jan. 17, 1992). The revised rule specifies that information is material if it is not "cumulative" and helps to establish a "*prima facie* case of unpatentability." 37 C.F.R. § 1.56(b) (2006).

Soon after the rule change, the PTO Commissioner who oversaw the rulemaking justified the change on the ground that the old "rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation." Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 140 (1992). But even at that time, there was some worry that the Federal Circuit would refuse to modify the judicial standard applied in inequitable conduct cases: "Only time will tell what the courts will do with the rule—whether they will follow it or not in considering questions of unenforceability." *Id.* at 143.

The Federal Circuit, however, has demonstrated its intent to maintain a broad and vague judicial standard of materiality notwithstanding the PTO's clarification of its standard. As set forth in the decision below (App. 11a n.6), the Federal Circuit has already held that the "'reasonable examiner' standard and [the] case law interpreting that standard were not supplanted by the PTO's adoption of a new rule 56." *Digital Control*, 437 F.3d at 1316. Consequently, the conflict between the Federal Circuit and the PTO presented by this case is identical to the conflict that would have been presented if the post-1992 rule had governed the prosecution of the patent-in-suit. This case, therefore, does indeed present an issue of continuing importance and an excellent vehicle for review of the inequitable conduct doctrine.[4]

The PTO's 1992 clarification of its materiality standard parallels a circumstance that this Court confronted in *Raquel v. Education Management Corp.*, 531 U.S. 952 (2000), where the Petitioner had been held by the court of appeals (then-Judge Alito dissenting) to have made a willful misstatement on the form for registering a copyright. On a petition for certiorari, this Court called for the views of the Solicitor General (CVSG). In response, the Copyright Office published a clarification of its administrative practice supporting the Petitioner's view that it had properly

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[4] Barr points repeatedly to the PTO's Manual of Patent Examining Procedure (MPEP), but that reference merely demonstrates the conflict. The MPEP told examiners to consider the declarant's "interest," MPEP § 716(3) (1983-1987), and more recent editions have made clear that "interest" refers to "the interest of the expert in the outcome of the case." MPEP § 716.01(c), at 700-288 (8th ed., rev. 5 2006). The experts here had no interest in the outcome of the case, and the Manual does not even hint that the expert's past relationships with the applicant should be disclosed.

disclosed the information necessary to register a copyright, and the Solicitor General recommended that this Court grant the petition, and vacate and remand the case for reconsideration in light of the views expressed in the Copyright Office's clarification. *See* Br. for the United States as Amicus Curiae in No. 99-1489, 17-19 (available at http://www.usdoj.gov/osg/briefs/2000/2pet/6invit/1999-1489.pet.ami.inv.pdf). This Court took that precise course of action. *See Raquel*, 531 U.S. at 952.

In summary, *Raquel* demonstrates that a court may consider an agency's clarification of its procedures when evaluating whether a procedural wrong has occurred, even where that clarification occurs after the administrative process is complete. *Raquel* also underscores the value of the CVSG process in confirming that a court's holding conflicts with the reality of an agency's processes. Accordingly, even though the 1992 PTO rule itself shows the agency's longstanding conflict with the Federal Circuit, a CVSG would provide the Court with additional information regarding the PTO's processes.[5]

CONCLUSION

For the reasons stated in the Petition and this reply, the Petition for a Writ of Certiorari should be granted.

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[5] This Court has recently used the CVSG process with greater frequency in patent cases, including "private disputes," contrary to Barr's contentions (*see* Resp. Br. 24 n.7). A good example is *Microsoft Corp. v. AT&T Corp.*, 126 S. Ct. 1901 (2006). Unlike here, no circuit split was alleged in that case and, prior to the filing of the SG's brief, the government had not indicated disagreement with the Federal Circuit. *See* Br. of the United States as Amicus Curiae in No. 05-1056 (filed Sept. 29, 2006).

Respectfully submitted,

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